Reynolds Medical Ltd.
510(k) Submission
CardioCollect
510(k) Summary

DEC 1 3 2001

(1) Submitter Information

Name: Reynolds Medical Ltd.

Address:

1 Harforde Court
John Tate Road
Hertford, Herts. SG13 7NW
ENGLAND

Telephone Number: 44-1992-507700

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: October 3, 2001

(2) Name of Device

Trade Name: CardioCollect
Common Name: Ambulatory electrocardiograph without analysis
Classification name: Electrocardiograph (74DPS, 870.2340)

(3) Equivalent legally-marketed devices.

Agilent M2662A, K002459

(4) Description

CardioCollect is a small, portable rechargeable-battery-powered digital electrocardiograph that is intended to be used by technicians to acquire 12-lead ECG's from up to 40 patients, and then print them or store them digitally in the patient's record in a computer (or both). The unit prints by direct connection to a

printer. Typical recording time is ten seconds; all leads are recorded simultaneously. The unit meets all specifications for 12-lead electrocardiographs. It has a provision for entry of patient data using its keypad.

Records include basic data on patients (name, number, and date of birth) as well as the electrocardiogram, and these can be printed with the tracing.

(5) Intended Use

The Reynolds CardioCollect is a small, portable rechargeable-battery-powered digital electrocardiograph that is intended to be used by technicians to acquire 12-lead ECG's from up to 40 patients, and then print them or store them digitally in the patient's record in a computer (or both).

(6) Performance Data

(a) Non-clinical tests

CardioCollect has passed the tests for ANSI/AAMI EC11, electrocardiographs, and EN 60601-1 (electrical safety) and EN 60601-1-2 (electromagnetic compatibility).

(b) Clinical tests

A series of electrocardiograms has been taken with CardioCollect to show the quality of the tracings made.

(c) Conclusions

CardioCollect is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2001

Reynolds Medical Ltd.
c/o George H. Myers, Sc.D.
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604

Re: K013367
Trade Name: CardioCollect Portable Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: October 8, 2001
Received: October 10, 2001

Dear Mr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known): K013367

Indications for Use Form

Device Name: CardioCollect

Indications for Use:

CardioCollect is a small, portable rechargeable-battery-powered digital electrocardiograph intended to be used by technicians to acquire 12-lead ECG's from up to 40 patients, and then print them or store them digitally in the patient's record in a computer (or both). The unit prints by direct connection to a printer. The unit meets all specifications for 12-lead electrocardiographs and has a provision for entry of patient data using its keypad.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-Counter Use**
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013367